

DATA EVALUATION RECORD

PAECILOMYCES FUMOSOROSEUS APOPKA STRAIN 97 (PFR-97 20% WDG)

STUDY TYPE: Request for Exemption From the Requirement of a Tolerance

No MRID Number

Prepared for
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U.S. Environmental Protection Agency
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Prepared by
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Oak Ridge, TN 37830
Task Order No. 10-013

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Date: _____

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Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

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DATA EVALUATION RECORD

EPA Secondary Reviewer: Ibrahim S. Barsoum, Ph.D.

STUDY TYPE:	Request for an Exemption from the Requirement of a Tolerance
MRID NO:	None
DECISION NO:	425259
DP BARCODE:	DP374463
TEST MATERIAL:	PFR-27 20% WDG (a.i., 20.0% <i>Paecilomyces fumosoroseus</i> Apopka Strain 97)
PROJECT STUDY NO:	Not provided
SPONSOR:	Certis U.S.A., L.L.C., 9145 Guilford Road, Suite 175, Columbia, MD 21046
TESTING FACILITY:	Not applicable
TITLE OF REPORT:	Petition Proposing an Exemption From the Requirement of a Tolerance for the Use of the Microbial Pest Control Agent <i>Paecilomyces fumosoroseus</i> Apopka Strain 97
AUTHOR:	Wagner, J.
STUDY COMPLETED:	December 14, 2009
CONFIDENTIALITY	
CLAIMS:	None.
GOOD LABORATORY PRACTICE:	Not applicable
CONCLUSION:	The petition supports the requested exemption from the requirement of a tolerance <i>Paecilomyces fumosoroseus</i> Apopka Strain 97 in/on all agricultural commodities.

Summary of Petition

Proposed Use

PFR-27 20% WDG is an end use product currently registered (EPA Reg. No. 70051-19) for control of insects and mites on ornamental plants grown in greenhouses and nurseries. The registrant proposes to amend the product label to allow use on vegetables, fruits, ornamental plants, and other crops grown either outdoors, in greenhouses or under other cover, or in nurseries. As a result, the registrant has submitted a petition for an exemption from the requirement of a tolerance for residues of the active ingredient, *Paecilomyces fumosoroseus* Apopka Strain 97, in/on all agricultural commodities.

Product Identity/Chemistry/Magnitude of the Residue

Paecilomyces fumosoroseus Apopka Strain 97 is a naturally-occurring entomopathogenic fungus that can infect and control several insect pests, including whiteflies, thrips, aphids, and spider mites. Under the proper environmental conditions, spores of the fungus penetrate the cuticle of the insect and grow inside it, causing its death. *Paecilomyces fumosoroseus* Apopka Strain 97 was originally isolated in 1986 from a mealybug in a greenhouse in Apopka, Florida. The pure culture was identified in 1988, and deposited at the American Type Culture Collection (ATCC #20874).

Since *Paecilomyces fumosoroseus* Apopka Strain 97 occurs naturally in soils worldwide, humans, other animals, and plants are constantly exposed to this fungus. Its use as proposed is not expected to result in residues that are of toxicological concern. *Paecilomyces fumosoroseus* Apopka Strain 97 is affected by sunlight, temperature, humidity, substrate, and chemicals, which reduces the potential for residues to occur. Normal washing after harvest and before sale would further reduce or remove any residues. There is a low probability of its germination on harvested crops in the absence of an insect host, which further reduces the chance of residues that are of toxicological concern.

Furthermore, any potentially-occurring residue on crops would not harm humans, since the strain shows no toxicity, infectivity, or pathogenicity in the appropriate tests. The optimal temperature range for growth, germination, and sporulation of the strain is 20 to 30°C, while the normal body temperatures of humans, other mammals, and avian species are significantly higher.

Paecilomyces fumosoroseus Apopka Strain 97 is produced using a liquid fermentation. Secondary metabolites such as beauverolides and beauvericine have been detected in still culture, but not in liquid fermentation.

Mammalian Toxicity Profile

Acute oral toxicity/pathogenicity – rat: an oral dose of 1.7×10^6 cfu/animal in a conidia spore suspension did not produce mortality or abnormal clinical effects. No signs of fungal contamination were reported for the brain, mesenteric lymph nodes, blood, kidney, spleen, liver, lung or cecum, and no infectivity or pathogenicity was recorded.

Acute intraperitoneal toxicity/pathogenicity – rat: Single intraperitoneal doses of suspensions containing 1.6×10^7 conidia spores per animal had no toxic or pathogenic effects and the spores were cleared from the body within two days.

Acute pulmonary toxicity/pathogenicity – rat: a single intratracheal dose (10^6 conidia spores/animal) resulted in no deaths and there were no signs of toxicity in any animal. No signs of infection were seen and no colonization of the lungs was observed. Total clearance of the fungus was attained by day eight after treatment. The product was classified as Toxicity Category IV.

Acute dermal toxicity/pathogenicity – rat: 2 grams of test substance applied to the skin of rabbits produced no deaths and there was no evidence of systemic toxicity. The product was classified as Toxicity Category III.

Primary eye irritation – rabbit: 0.1 mL of diluted test substance containing $\geq 10^7$ cfu was instilled in the eye, which was examined at 1, 24, 48 and 72 hours, and at 4 and 7 days after treatment. The test substance produced slight irritation which was reversible by day 4 after treatment. The product was classified as Toxicity Category IV.

Dermal irritation – rabbit: in a four-hour exposure, the test substance (2 g/animal) was found to be a slight dermal irritant. The product was classified the product as Toxicity Category IV.

Dermal sensitization – guinea pig: The test substance ($3.0 \times 10^7 - 5.3 \times 10^9$ cfu) produced no

irritation or sensitization reaction in treated animals. The product was not a dermal sensitizer.

Mutagenicity Test on *Salmonella typhimurium* (Ames Assay): Sonicated blastospores and mycelium of *Paecilomyces fumosoroseus* Apopka strain 97 (100 – 5000 µg/plate) yielded negative results in a reverse mutation assay in both the presence and absence of microsomal enzymes (S9).

Aggregate Exposure

Food

It is expected that, when used as proposed, *Paecilomyces fumosoroseus* Apopka strain 97 will not result in residues that are of toxicological concern. Its growth and survival is affected by sunlight, temperature, humidity, substrate, and chemicals, especially fungicides. After harvest, any remaining spores on crops will be exposed to unfavorable conditions (e.g. dryness), and are not likely to germinate and grow on the harvested crop. Any potential residues on these crops will not harm humans because the fungal strain shows no toxicity, infectivity, or pathogenicity in appropriate tests.

Further, the optimal temperature range for growth, germination and sporulation is between 20 and 30°C while the normal body temperatures of humans, other mammalian species and avian species are significantly higher and unsuitable for growth and reproduction of *Paecilomyces fumosoroseus* Apopka strain 97.

While the proposed use pattern may result in dietary exposure with possible residues in or on certain agricultural commodities, negligible to no risk is expected for the general population, including infants and children, or animals because *Paecilomyces fumosoroseus* Apopka strain 97 demonstrated no pathogenicity or toxicity at the maximum doses tested, generally limit doses.

Drinking Water

Paecilomyces fumosoroseus Apopka strain 97 is not known as an aquatic microorganism, and is not expected to proliferate in aquatic habitats. There are no aquatic use sites permitted for this pesticide, so exposure to drinking water is not expected. Percolation through soil and municipal treatment of drinking water would reduce the possibility of exposure to *Paecilomyces fumosoroseus* Apopka strain 97 via drinking water. The potential of significant transfer to drinking water is minimal to nonexistent. Even if low levels of the microbe were present in drinking water, no risk to the general public would be expected because *Paecilomyces fumosoroseus* Apopka strain 97 demonstrated no pathogenicity or toxicity at the maximum dose tested.

Non-Dietary Exposure

Since *Paecilomyces fumosoroseus* Apopka strain 97 occurs naturally, there may be non-dietary exposure from background levels. Humans may be exposed dermally or orally via soil on their hands or clothing, or by handling pets that have played in soil. However, no toxicological endpoints were identified for *Paecilomyces fumosoroseus* Apopka strain 97, and there is no

evidence of adverse effects from oral, dermal, or pulmonary exposure. It is not expected that the pesticidal use of *Paecilomyces fumosoroseus* Apopka strain 97 will significantly increase the non-dietary and non-occupational exposure to the fungus.

Based on the proposed use patterns, the potential for non-dietary, non-occupational exposures to residues by the general population, including infants and children, is low.

Cumulative Exposure/Determination of Safety for U.S. Population, Infants, and Children

There is reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposures to residues of *Paecilomyces fumosoroseus* Apopka strain 97 as a result of its proposed uses. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. There appears to be no potential for harm from this fungus in its use as a microbial pesticide in agricultural commodities. Furthermore, the organism is non-toxic and non-pathogenic to animals and humans, based on the results of the mammalian toxicity tests. Moreover, potential non-occupational inhalation or dermal exposure is not expected to pose any adverse effects to exposed populations via aggregate and cumulative exposure.

Effects on Immune and Endocrine Systems

There is no information to indicate that *Paecilomyces fumosoroseus* Apopka strain 97 would have an effect in humans similar to an effect produced by a naturally-occurring estrogen or other endocrine effects. There is no known metabolite produced by this fungus that acts as an endocrine disruptor. The submitted toxicity/pathogenicity studies in rodents indicate that no viable conidia or blastospores were found in organs or tissues of the test animals. It is concluded that there will be no incremental adverse effects to the endocrine system.

Existing Tolerances

None.

International Tolerances

The European Food Safety Authority Scientific Report (2007), 115, 1-161, determined that under Regulation (EC) No 396/2005 of the European Parliament and of the Council on Maximum Residue Levels for pesticides (28 October 2007) that no MRLs and no residue definitions have to be established for the use of *Paecilomyces fumosoroseus* Apopka strain 97 on agricultural crops.

Reviewers' Comments

The reviewers believe the registrant's petition supports the requested exemption from the requirement of a tolerance provided that the registrant test for beauverolides in production batches.